Section E

510(k) Summary

K033224

E. 510(k) Summary

E.1 Company Identification

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730
781-999-7300

E.2 Contact Information

Daniel F. Phelan
Senior Regulatory Affairs Specialist

E.3 Date of Submission

October 3, 2003

E.4 Device Identification

Proprietary Name	Hologic QDR Explorer X-Ray Bone Densitometer
Classification Name:	Bone Densitometer
Common/Usual Name	Bone Densitometer
Regulation Number:	21 CFR 892.1170
Product Code:	90 KGI
Classification	II
Classification Panel	Radiology

E.5 Predicate Device Information

K943505	Hologic QDR-3000 X-Ray Bone Densitometer
K023398	Hologic Discovery Package for QDR X-Ray Bone Densitometers

E.6 Device Description and Intended Use

The Hologic QDR Explorer is a fan beam X-Ray Bone Densitometer indicated for (1) the measurement of bone mineral content (BMC) and the estimation of bone mineral density (BMD), (2) comparison of measurements to reference databases, (3) the estimation of fracture risk, (4) body composition analysis, and (5) measurement of periproshtetic BMD.

K033224

E.7 Substantial Equivalence

	QDR-3000	QDR Explorer
510(k) Number	K943505	[redacted]
System Footprint	3.02m (119 in) L x 1.50m (59 in) W x 1.42m (56 in) H +/- 25mm (1 in).	Same
System Weight	320 kg (720 lb)	327 kg (729 lb)
System Power Requirements	100V (23A), 120V (18A), and 230V (9A) models available	Same
X-Ray Tube	Switched pulse dual-energy x-ray tube operating at 100 kV and 140 kV. 2.5 mA average at 25% duty cycle. Tungsten target	Same.
Detector Array	64 multichannel detector consisting of $CdWO_4$ scintillators coupled to silicon diodes	54 multichannel detector consisting of $CdWO_4$ scintillators coupled to silicon diodes
X-Ray Source-to-Image-Detector Distance	1070 mm (42 in) +/- 8 mm (0.315 in)	883.4 mm (34.8 in) +/- 8 mm (0.315 in)
X-Ray Source-to-Patient Distance	424 mm (16.7 in) +/- 6 mm (0.236 in)	Same
Collimation	Aperture with 1.0 mm slit.	Same
Laser Positioning Device	Laser diode < 1mW cross hair with emergency mechanical shutter.	Same
Leakage Radiation	The QDR-3000 meets the requirements of 21 CFR 1020.30(k) for leakage from the x-ray source.	The QDR Explorer meets the requirements of 21 CFR 1020.30(k) for leakage from the x-ray source
Scatter Radiation	10μGy/hr at 1m from the examination table (Nominal)	Same
Scan Time	15 seconds – 407 seconds, depending on scan mode	62 seconds – 403 seconds, depending on scan mode
Scan Sites	Lumbar spine (L1, L2, L3, L4), Proximal femur (hip), Forearm (radius and ulna), Whole body	Same
Software Operating System	Hologic Eagle Software Windows 98-Based Operating System (K992677)	Hologic Discovery Software Package Windows XP-Based Operating System (K023398)
PC Hardware Requirements	≥ 1.0 GHz processor	≥ 1.5 GHz processor
	≥ 256 MB RAM	Same
	≥ 20 GB hard disk	Same
	3.5" 1.44 MB diskette drive	Same
	17" monitor (CRT)	17" monitor (CRT or LCD)
	120 MB SuperDisk drive	CD/RW drive
	CD-ROM drive	N/A
	16 MB video card	Same
	Standard keyboard and mouse	Same
BMC Measurement	Standard	Same
BMD Measurement	Standard	Same
Fracture Risk Estimation (K983028)	Standard	Same
Reference Databases (K963363)	Standard	Same
Body Composition Analysis (K961787)	Optional	Same
Periprosthetic BMD Measurement (K002711)	Optional	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

Mr. Daniel F. Phelan
Senior Regulatory Affairs Specialist
Hologic, Inc.
35 Crosby Drive
BEDFORD MA 01730-1401

Re: K033224
Trade/Device Name: Hologic QDR X-Ray Bone Densitometer
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: 90 KGI
Dated: October 3, 2003
Received: October 6, 2003

Dear Mr. Phelan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

A.2 Indications for Use Statement

510(k) Number (if known): K033224

Device Name: Hologic QDR Explorer X-Ray Bone Densitometer

Indications for Use:

The Hologic QDR Explorer is a fan beam X-Ray Bone Densitometer indicated for (1) the measurement of bone mineral content (BMC) and the estimation of bone mineral density (BMD), (2) comparison of measurements to reference databases, (3) the estimation of fracture risk, (4) body composition analysis, and (5) measurement of periprosthetic BMD

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use

(Per 21 CFR 801.109) (Optional Format 1)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033224